DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

HFV-232

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SEP 16 1999

WARNING LETTER
CVM 99-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Andrew T. Palmeter, D.V.M.
Associate Director, Regulatory Affairs
Fort Dodge Animal Health
Cyanamid Agricultural Center
P.O. Box 400
Princeton, New Jersey 08543 - 0400

Dear Dr. Palmeter:

We have reviewed an advertisement stating in part "Introducing the new breed of long-acting parasite control - Cydectin (moxidectin) Pour-On, Now approved for lactating dairy cattle" which appeared as a four and one-half page insert in the September 1999 issue of "Dairy Today."

Cydectin (moxidectin) for animal use is a new animal drug as defined by Section 201(v) of the Federal Food, Drug, and Cosmetic Act (the Act). There is no approved New Animal Drug Application (NADA) on file for use of this product in lactating dairy cattle. Advertisement or promotion of this new animal drug for this unapproved use causes the drug to be misbranded under Section 502(f)(1) of the Act in that the product is intended for use in lactating dairy animals but fails to bear adequate directions for that use. Adequate directions for use cannot be written because no one knows what adequate directions might be since there is no approved NADA on file for this use.

Our records show that Fort Dodge Animal Health has been notified of promotion and advertising violations for other new animal drug products. CVM discussed these kinds of violations with you in a meeting on September 4, 1998, and again brought these kinds of violations to your attention in letters dated as recently as August 4 and 17, 1999. Although Fort Dodge has committed to discontinuing this violative activity, we find it occurring again with the Cydectin product.

This letter is not intended to be a complete review of all of your firm's products. It addresses a recent violation involving one product. It is your responsibility to ensure that all products marketed by your firm are in compliance with requirements of the Act and it's implementing regulations.

We request that you take prompt action to correct this violation. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against a manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the violation. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Judith Gushee, Team Leader, Drug and Device Team (HFV-232), Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, Maryland 20855, telephone number 301-827-0150.

Sincerely yours,

Gloria J. Dunnavan

Gloria J. Dunnavan
Director
Division of Compliance, HFV-230
Office of Surveillance and Compliance
Center for Veterinary Medicine

cc: John R. Stafford, Chairman, President, and CEO
American Home Products Corporation
5 Giralda Farms
Madison, New Jersey 07840